CATHETER WITH THIN-WALLED BRAID

Technical Field

The invention relates generally to elongate medical devices and more particularly to catheters having braided or other reinforcement elements.

Background of the Invention

Reinforcing layers such as reinforcing braid layers can provide thin-walled catheters with desired resistance to kinking while retaining desirable flexibility. In some instances, it can be desirable for portions of a thin-walled catheter to be either more flexible or less flexible than other portions of the catheter. In particular, it can be desirable for a distal portion of a catheter to be more flexible, especially if the distal portion of the catheter is curved. However, a reinforcing braid layer that can provide suitable kink resistance in other portions of a catheter may not provide sufficient flexibility in the distal portion of the catheter.

A need remains for improved catheters having desirable kink resistance while being sufficiently flexible, particularly in distal portions that can be curved in use, especially when tracking dramatic bends in the vasculature of an individual.

Summary of the Invention

The present invention is directed to a catheter braid that can be woven from continuous wires. A portion of each wire can have a diameter that is reduced with respect to another portion of that wire.

Accordingly, an exemplary embodiment of the invention can be found in a catheter braid that is formed from at least two continuous wires that are woven together. The catheter braid can include a proximal braid section in which each of the continuous

wires have a proximal diameter, and a distal braid section in which each of the continuous wires have a distal diameter. For each continuous wire, in one preferred embodiment, the distal diameter of the continuous wire is less than the proximal diameter of the continuous wire.

Another example embodiment of the invention can be found in a catheter that has a distal end and a proximal end, and a distal region that is proximate the distal end. The catheter can include an inner layer that extends from the distal end to the proximal end, and a reinforcing braid layer that can be disposed over the inner layer. The braid layer can be formed from at least two continuous wires that are woven together. The braid layer can have a proximal braid section in which each of the continuous wires have a proximal diameter, and a distal braid section in which each of the continuous wires have a distal diameter. The distal diameter of each continuous wire, in one preferred embodiment, is less than the proximal diameter of each continuous wire.

An example embodiment of the invention can also be found in a method of forming a catheter that has a distal end and a proximal end. The catheter can include an inner layer and a braid layer. The catheter can be formed by weaving together at least two continuous wires to form the braid layer. The formed braid layer distal portion is then, in a preferred embodiment, immersed in an etching solution to thin the wires to a desired reduced diameter. The resulting braid layer has a proximal section in which each of the wires has a proximal diameter and a distal section in which each of the wires has a distal diameter that is less than the proximal diameter. The braid layer, once formed, can be positioned over the inner layer.

Brief Description of the Drawings

Figure 1 is a plan view of a catheter in accordance with an embodiment of the invention;

Figure 2 is a cross-sectional view of the catheter of Figure 1 taken along line 2-2;

Figure 3 is a partially sectioned view of the catheter of Figure 1;

Figure 4 is a partially sectioned cutaway view of a portion of a woven braid in accordance with an embodiment of the invention;

Figure 5 is a partially-sectioned view of a portion of a woven braid, in accordance with an embodiment of the invention; and

Figure 6 is a partially sectioned view of the catheter of a distal portion of the catheter of Figure 1.

Detailed Description of the Preferred Embodiments

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about", whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As

used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The drawings, which are not necessarily to scale, depict illustrative embodiments of the claimed invention.

Figure 1 is a plan view of a catheter 10 in accordance with an embodiment of the invention. The catheter 10 can be any of a variety of different catheters. In some embodiments, the catheter 10 can be an intravascular catheter. Examples of intravascular catheters include balloon catheters, atherectomy catheters, drug delivery catheters, diagnostic catheters and guide catheters. The intravascular catheter 10 can be sized in accordance with its intended use. The catheter 10 can have a length that is in the range of about 50 to about 150 centimeters, preferably in the range of about 100 to about 150 centimeters, and can have any useful diameter. As illustrated, Figure 1 portrays a guide catheter, but the invention is not limited to such. Preferred methods of manufacture are described herein. The catheter 10 can also be manufactured using conventional techniques.

In the illustrated embodiment, the intravascular catheter 10 includes an elongate shaft 12 that has a proximal end 14 and a distal end 16. A hub and strain relief assembly 18 can be connected to the proximal end 14 of the elongate shaft 12. The hub and strain relief assembly 18 includes a main body portion 20, and a strain relief 24 that is intended to reduce kinking. The hub can also include a pair of flanges 22. The hub and strain relief assembly 18 can be of conventional design and can be attached using conventional

techniques.

The elongate shaft 12 can include one or more shaft segments having varying degrees of flexibility. As illustrated, the elongate shaft 12 includes a first shaft segment 26, a second shaft segment 28 and a third shaft segment 30. In some embodiments, the elongate shaft 12 can include fewer shaft segments or only one shaft segment or can include more than three segments, depending on the flexibility requirements of a particular application.

Figure 2 is a cross-sectional view of the elongate shaft 12, taken along the line 2-2 of Figure 1, while Figure 3 is a longitudinal cross-sectional view of a portion of the elongate shaft 12. The proximal portions of the elongate shaft 12, as illustrated, include an outer layer 34 and an inner layer 36, and can include a reinforcement layer 38 that is positioned between the inner layer 36 and the outer layer 34. The inner layer 36 defines a lumen 40 that extends through the elongate shaft 12. The distal portion 32 of the elongate shaft 12 will be discussed in greater detail hereinafter.

Each of the shaft segments 26, 28, 30 can have a similar construction. In particular, each of the shaft segments 26, 28, 30 can include an inner layer 36, a reinforcing layer 38 that is the same for or continuous through each of the shaft segments 26, 28, 30 and an outer layer 34 that becomes more flexible in the shaft segments 26, 28, 30 closest to the distal end 16 of the catheter 10. For example, the proximal shaft segment 26 can have an outer layer that is formed from a polymer having a hardness of 72D (Durometer), the intermediate shaft segment 28 can have an outer layer having a hardness of 68D and the distal shaft segment 30 can have an outer layer having a hardness of 46D.

Each of the shaft segments 26, 28, 30 can be sized in accordance with the intended function of the resulting catheter 10. For example, the shaft segment 26 can have a length of about 35 inches, the shaft segment 28 can have a length in the range of about 2 to 3 inches and the shaft segment 30 can have a length in the range of about 1 to 1.25 inches.

The shaft segments 26, 28, 30 can be formed of any suitable material such as a polymeric material. Examples of suitable polymer material include any of a broad variety of polymers generally known for use as polymer sleeves or tubular members. In some embodiments, the polymer material used is a thermoplastic polymer material. Some examples of some suitable materials include polyurethane, elastomeric polyamides, block polyamide/ethers, polyester/ethers, silicones, and blends such as PBT/Arnitel® blends and PBT/Hytrel® blends. One preferred polymer is a polyurethane (PUR) and polyoxymethylene (POM or Delrin®) blend.

In some embodiments, the inner layer 36 can be a single piece uniform material extending over the length of the shaft 12 and can define a lumen 40 that can run the entire length of the elongate shaft 12 and that is in fluid communication with a lumen (not illustrated) extending through the hub assembly 18. The lumen 40 defined by the inner layer 36 can provide passage to a variety of different medical devices or fluids, and thus the inner layer 36 can be manufactured from or include a lubricious material to reduce friction within the lumen 40. Examples of suitable materials include polytetrafluoroethylene (PTFE), such as TEFLON®. The inner layer 36 can be dimensioned to define a lumen 40 having an appropriate inner diameter to accommodate its intended use. In some embodiments, the inner layer 36 can define a lumen 40 having

a diameter of about 0.058 inches and can have a wall thickness of about 0.001 to about 0.0015 inches.

In some embodiments, the outer layer 34 can include a portion made from a thermoplastic polymer such as a co-polyester thermoplastic polymer such as that available commercially under the ARNITEL® name. The use of an ARNITEL® polymer is described in detail below. The outer layer 34 can have an inner diameter that is about equal to the outer diameter of the inner layer 36. The outer layer 34 can have an inner diameter that is slightly greater than the outer diameter of the inner layer 36 to accommodate the thickness of the reinforcing braid layer 38. In some embodiments, the outer layer 34 can have an inner diameter in the range of about 0.0600 to 0.0618 inches and an outer diameter in the range of about 0.0675 to 0.0690 inches.

In some embodiments, the outer layer 34 or portions thereof can include or be filled with radiopaque material to make the outer layer 34 or portions thereof more visible when using certain imaging techniques, for example, fluoroscopy techniques. Any suitable radiopaque material known in the art can be used. Some examples include precious metals, tungsten, barium subcarbonate powder, and the like, and mixtures thereof. In some embodiments, the polymer can include different sections having different amounts of loading with radiopaque material. For example, the outer layer 34 can include a distal section having a higher level of radiopaque material loading, and a proximal section having a correspondingly lower level of loading.

A reinforcing braid layer 38 can be positioned between the inner layer 36 and the outer layer 34. The reinforcing braid layer 38 can be formed of any suitable material, including metals and metal alloys. In some embodiments, the reinforcing braid layer 38

can include a metal wire braid (with wires that are round, flat, or other cross-sectional shape) formed of stainless steel, tungsten, gold, titanium, silver, copper, platinum, or iridium. The reinforcing braid layer 38 can also be formed from non-metallic material such as KEVLAR® (poly paraphenylene terephthalamide) fibers, LCP (liquid crystal polymer) fibers or glass fibers. In some embodiments, the reinforcing braid layer 38 can be formed of a high tensile stainless steel such as 304V stainless steel.

In some embodiments, the reinforcing braid layer 38 can extend over substantially the entire length of the catheter 10. The reinforcing braid layer 38 can extend from a position proximate to or distal of the proximal end 14 of the elongate shaft 12 to a position proximate to or proximal of the distal end 16 of the elongate shaft 12.

As illustrated for example in Figure 4, a reinforcing braid 42 can be formed of several continuous fibers. In some embodiments, the reinforcing braid 42 can be formed by weaving together two or more continuous wires over a mandrel 41. The continuous wires can be flat or round in cross-section and can be woven together in a variety of patterns. The reinforcing braid 42 can be formed by weaving together two continuous wires 44 and 46, as illustrated.

However, the invention contemplates, for example, using three continuous wires woven together in a three-over-three pattern, while other patterns such as a four-over-four, two-over-four, or even a five-over-five pattern can also be used, depending on the number of wires used. In particular, the wires can have a round cross section having a diameter of about 1.0 to about 2.0 millimeters. The braid can also be formed with flat or other non-round cross sections. If such braid is used, the cross section reduces in dimension, such as width and height, versus diameter for a round wire.

A reinforcing braid 42 can be formed by weaving together two continuous wires 44 and 46 that have cross-sectional diameters that are at least substantially constant from a proximal end 48 of the reinforcing braid 42 to a distal end 50 of the reinforcing braid 42. As used herein, a continuous wire is a single wire that extends from one end of the braid to the other end of the braid, without splicing, welding or any other means of joining two wires together. A continuous wire can have a constant diameter across its entire length. A continuous wire can have a diameter that changes along its length. The diameter can vary continuously, or the diameter can vary step-wise.

In some embodiments, each of the continuous wires 44, 46 can have the same diameter. In other embodiments, not illustrated, it is contemplated that one continuous wire 44 can have a first constant diameter, while the second continuous wire 46 has a second constant diameter that is either greater or less than the first constant diameter.

Forming a braid 42 from continuous wires 44, 46 of constant diameter can produce a braid 42 having uniform flexibility, torque transmission and other useful performance parameters. In some embodiments, a braid 42 as illustrated in Figure 4 can be used in part or all of a catheter 10 and forms the reinforcing braid layer 38 illustrated in the earlier Figures. In some embodiments, the braid 42 can extend from the proximal end 14 of the elongate shaft 12 to a point proximal of the distal end 16 of the elongate shaft 12.

In some embodiments it can be desirable for a portion of the braid 42 to be more flexible than another portion of the braid 42. It may be useful for the distal portion 50 of the braid 42 to be more flexible than the proximal portion 48. For example, catheters can have a distal portion 32 that can be curved, as indicated in Figure 6. In some

embodiments, the distal portion 32 can curve in response to anatomical features encountered in use. In other embodiments, the distal portion 32 can be pre-bent or pre-curved prior to use. In order to more easily curve, it can be useful for any braid present in the distal portion 32 to be more flexible.

Figure 5 illustrates an embodiment of a reinforcing braid 52 that can be formed, as described above with respect to Figure 4, by weaving together two or more continuous wires 58 and 60 over a mandrel 41. The braid 52 shown in Figure 5 has a proximal portion 54 in which each of the continuous wires 58, 60 have a proximal diameter D1 and a distal portion 56 in which each of the continuous wires 58, 60 have a distal diameter D2.

In the illustrated embodiment, the distal diameter D2 is less than the proximal diameter D1. In some embodiments, the distal diameter D2 can be about one-third less than the proximal diameter D1. In a particular embodiment, the proximal diameter D1 can be about 1.5 millimeters, while the distal diameter D2 is about 1.0 millimeters. The use of diameter is illustrative of a round wire, although other shaped wire can be used with commensurate change in cross-sectional area.

As can be seen in Figure 6, the reinforcing braid 52 can be positioned within a catheter portion 32 such that the proximal portion 54 of the braid corresponds to a more proximal section 62 of the catheter portion 32, while the distal portion 56 of the braid 52 corresponds to a curved, more distal section 64 of the catheter portion 32. As a result, the catheter portion 32 can be more flexible and supportive. In some embodiments, the reinforcing braid 52 can extend proximally to the proximal end 14 of the elongate shaft 12. In such embodiments, the proximal portion 54 forms the reinforcing braid layer 38.

The reinforcing braid 52 shown in Figure 6 can be formed in a variety of ways. In some embodiments, the braid 52 can be formed from two continuous wires 58, 60, each having equal, constant diameters. The distal portion 56 of the braid 52 can then be subjected to a procedure that will reduce the diameter of the wires 58, 60 within the distal portion 56 of the braid 52. A number of procedures are contemplated, although electro-etching is preferred.

In other embodiments, the braid 52 can be formed from two continuous wires 58, 60 that do not have constant diameters. In particular, each of the two continuous wires 58, 60 can be formed having a first portion having a first diameter and a second portion having a second, reduced diameter. The first diameter can correspond to the proximal diameter of the continuous wires 58, 60, while the second diameter can correspond to the distal diameter of the continuous wires 58, 60. The continuous wires 58, 60 can have a gradual transition between the first and second diameters. The wires 58, 60 can also be formed having a more abrupt transition between the first and second diameters. The wires 58, 60 can be formed using any of a variety of procedures, although cold-drawing is preferred.

Once the braid 52 has been formed, it can be incorporated into a catheter 10. An inner layer 36 can be placed on a mandrel. The braid 52 can be positioned over the inner layer 36 by axially compressing the braid 52. This enlarges the inner diameter of the braid 52 and permits easy positioning of the braid 52 over the inner layer 36. Once the braid 52 has been positioned to form the reinforcing braid layer 38, an outer layer 34 can be installed if desired. The outer layer 34 can be co-extruded over the reinforcing braid layer 38, or it can be pre-formed and then heat shrunk into position.

In at least some embodiments, portions or all of the reinforcing braid layer 38 can include a radiopaque material. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like.

In some embodiments, a degree of MRI compatibility can be imparted. For example, to enhance compatibility with Magnetic Resonance Imaging (MRI) machines, it may be desirable to make the reinforcing braid layer 38, or other portions thereof, in a manner that would impart a degree of MRI compatibility. For example, the reinforcing braid layer 38 or portions thereof may be made of a material that does not substantially distort the image and create substantial artifacts, which are gaps in the image. Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. The reinforcing braid layer 38 or portions thereof may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, Elgiloy, MP35N, nitinol, and the like, and others.

An intravascular catheter 10 can optionally include a coating layer such as a lubricious coating layer over part or all of the catheter 10. Suitable lubricious polymers are well known in the art and can include hydrophilic polymers such as polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The scope of the invention is, of course, defined in the language in which the appended claims are expressed.